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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,142

Applicant(s)

CAMPBELL, ANTHONY KEITH

Examiner

Frank W Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,9,10,15-17 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 and 33 is/are allowed.
- 6) ☒ Claim(s) 1,6,7,9,10 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Response to Amendment***

1. Applicant's response to the office action filed on November 24, 2004 has been entered. The claims pending in this application are claims 1, 4-7, 9, 10, 15-17, and 31-33. Newly submitted claim 31 is directed to a method for detecting, diagnosing, or measuring oxygen or a metabolite in a substrate, which is an invention that is independent or distinct from the invention originally claimed because claim 1 and claim 31 are no longer linked by a special technical feature since an isolated, purified recombinant nucleic acid sequence recited in (b) of claim 1 is known in the art (Poly (dT) primer with 5-30 T (see US Patent No. 5,643, 766, column 5, Table 1 and lines 55-57)). Furthermore, amended claims 4 and 5 now are directed to a pholasin protein which is an invention that is independent or distinct from the invention originally claimed because claim 1 and claims 4 and 5 are no longer linked by a special technical feature since an isolated, purified recombinant nucleic acid sequence recited in (b) of claim 1 is known in the art (Poly (dT) primer with 5-30 T (see US Patent No. 5,643, 766, column 5, Table 1 and lines 55-57)). Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 4, 5, and 31 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Therefore, claims 1, 6, 7, 9, 10, 15-17, 32, and 33 will be examined. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on November 24, 2004.

Specification

2. The disclosure is objected to because of the following informalities: (1) although applicant attempts to insert "BRIEF DESCRIPTION OF THE FIGURES" in lines 5 and 7 of page 4 of the specification in the amendment filed on November 24, 2004. In view of page 4 of specification, it appears that lines 5 and 7 of page 4 of the specification is not a proper location to insert "BRIEF DESCRIPTION OF THE FIGURES"; and (2) there are several amino acid sequences with 4 or more amino acids in the specification (see Table 1 in page 6, pages 7, 8, 11, 12, and 20). However, these sequences have no SEQ ID Nos in the specification.

Appropriate correction is required.

Response to Arguments

In page 6, last paragraph bridging to page 7, first paragraph of applicant's remarks, applicant argues that "[A]s the sequences recited the present specification that are not identified by sequence identification number, applicant notes that Table 1 shows various motifs and a variety of proteins that are compared with the proteins of the present invention in order to elucidate the functional significance of various sequences within the cloned protein. This is also true of the information found on pages 7 and 8 of the present specification. As a result, applicant does not believe that a substitute sequence listing is required".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, since the amino acid sequences in Table 1 of page 6 and pages 7, 8, 11, 12, and 20 have more than four amino acids, according to 37 C.F.R 1.821-1.825, applicant must provide sequencing listings for these amino acid sequences. Second, applicant does not indicate

Art Unit: 1634

which part of MPEP suggests that applicant does not require to provide sequencing listings for these amino acid sequences if these amino acid sequences are used for comparison.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. New Matter

Claims 1, 6, 9, 10, and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed composition/or methods are not described in the instant disclosure, claims 1, 6, 9, 10, and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The recitation “a sequence at least 70% homologous to SEQ ID NO: 1” is added to the newly amended independent claim 1 and the recitation “invertebrate organism” is added to the newly amended independent claim 15. However, the specification fails to define or provide any

Art Unit: 1634

disclosure to support such claim recitation. Furthermore, in applicant's remarks filed on November 24, 2004, applicant does not indicate which part in the specification supports such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

5. Written Description

Claims 1, 6, 9, 10, and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the

Art Unit: 1634

‘written description’ inquiry, whatever is now claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (page 50 and sequencing listing) provides adequate written descriptions for SEQ ID NO: 1, which is full length cDNA of pholasin, a bioluminescent protein from bivalve mollusc *pholas dactylus* (see the specification, sequencing list and The Journal of Biological Chemistry, 275, 9403-9409, 2000). However, the specification fails to adequately describe an isolated nucleic acid sequence comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1 as recited in claims 1, 6, 9, 10, and 15-17. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells, Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In this instant case, although the specification adequately describes for SEQ ID NO: 1, which is full length cDNA of pholasin, a bioluminescent protein from bivalve mollusc *pholas dactylus* (see the specification, sequencing list and The Journal of Biological Chemistry, 275,

Art Unit: 1634

9403-9409, 2000), the specification fails to adequately describe an isolated nucleic acid sequence comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1 as recited in claims 1, 6, 9, 10, and 15-17. Since claim 1 can be read as an isolated nucleic acid sequence comprising any kind of sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1, claims 1, 6, 9, 10, and 15-17 encompass numerous unknown and unidentified nucleic acids that have polynucleotide sequence adding to 5', 3' and/or within the nucleotide sequence of SEQ ID No. 1 or numerous unknown and unidentified nucleic acids that can hybridize with SEQ ID No. 1, which miss from the disclosure. It is unclear what kinds of functions of these unknown and unidentified nucleic acids have. Furthermore, claim 15 is directed to any kind of invertebrate organism comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 or a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1. Although the specification indicates that transgenic animals such as transgenic mice can be generated from pholasin cDNA, the specification does not describe specification does not show any kind of invertebrate organism having observed phenotype comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 or a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific

Art Unit: 1634

for any of the sequences specified in (a) or (b) of claim 1. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all above possible isolated nucleic acids and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

6. Enablement

Claims 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing cell, plasmid or virus comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1, does not reasonably provide enablement for: (1) producing any kind of invertebrate organism comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1, and (2) producing

Art Unit: 1634

any kind cell, plasmid, virus or invertebrate organism comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to produce any kind of invertebrate organism comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 and produce any kind cell, plasmid, virus or invertebrate organism comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether any kind of invertebrate organism comprising an isolated or purified or recombinant nucleic acid

Art Unit: 1634

sequence comprising SEQ ID NO: 1 and any kind cell, plasmid, virus or invertebrate organism comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1 can be produced.

Claims 15 and 17 are directly to any kind cell, plasmid, virus or invertebrate organism comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 or a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1. The specification only describes to produce cell, plasmid or virus comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 (see the specification, pages 16-28). However, the specification does not provide a guidance to produce any kind of invertebrate organism comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 and produce any kind cell, plasmid, virus or invertebrate organism comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1. First, although the specification indicates that transgenic animals such as transgenic mice can be generated from pholasin cDNA, the specification does not provide an evidence to show that a transgenic mouse of pholasin has made. It is known that the state of the art in the fields of transgenic animal at the time of the invention was unpredictable, the transgene expression and resulting phenotype of such expression is not always accurately predictable. For example, Sigmund, June 2000 (Arterioscler.

Art Unit: 1634

Thromb. Vasc. Biol., p. 1425-1429), reports that variation in the genetic background contributes to unpredictable resulting phenotypes of transgenic or gene-targeted animals. "Animals containing the same exact genetic manipulation exhibit profoundly different phenotypes when present on diverse genetic backgrounds, demonstrating that genes unrelated, per se, to the ones being targeted can play a significant role in the observed phenotype" (abstract). Sigmund further states that "many of the phenotypes examined in transgenic and knockout models are influenced by the genetic background in which they are studies...Although all mouse strains contain the same collection of genes, it is allelic variation...and the interaction between allelic variants that influence a particular phenotype. These "epigenetic" effects can dramatically alter the observed phenotype and therefore can influence or alter the conclusions drawn from experiments" (e.g. introduction). Furthermore, the specification does not show that an invertebrate organism having observed phenotype comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 or a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1 can be made. Second, since claim 15 is directed to any kind cell, plasmid, virus or invertebrate organism comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1 and the specification does not provide any kind of sequence comprising at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1, it is

Art Unit: 1634

impossible to make any kind cell, plasmid, virus comprising at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1.

With these unpredictable factors, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. These undue experimentation at least includes to test whether: (1) any kind of invertebrate organism comprising an isolated or purified or recombinant nucleic acid sequence comprising SEQ ID NO: 1 can be produced; and (2) any kind cell, plasmid, virus or invertebrate organism comprising a sequence at least 70% homologous to SEQ ID NO: 1 or any kind of sequence that hybridizes to SEQ ID NO: 1 under stringency conditions or any kind of oligonucleotide specific for any of the sequences specified in (a) or (b) of claim 1 can be produced.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 6, 7, 9, 10, and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is rejected as vague and indefinite in view of (a) of the claim because SEQ ID NO: 1 does not encode an apophotoprotein of pholasin but encodes pholasin (see claims 4, 5, and 7). Please clarify.

Art Unit: 1634

10. The term “stringent conditions” in claim 1 is a relative term which renders the claim indefinite. The term “stringent conditions” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Note that the specification does not define “stringent conditions”. Please clarify.

Response to Arguments

In page 9, last paragraph of applicant’s remarks, applicant argues that “[A]s the term ‘stringent conditions’, applicant submits that one skilled the art would know what these conditions are and indeed would use such conditions daily in order undertake hybridization techniques. As a result, applicant believes that the term is definite to one skilled in the art”.

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since there is no definition for “stringent conditions” in the specification, “stringent conditions” is variable for one skilled in the art. Therefore, the term “stringent conditions” in claim 1 is a relative.

11. Claim 7 is rejected as vague and indefinite in view of the phrase “whose expression in a substrate, in association with a luciferin, signals the presence of oxygen or an oxygen metabolite in the substrate by producing a light signal” because this phrase is not a complete sentence and does not make sense. Please clarify.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1634

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheele *et al.*, (US Patent No. 5,643, 766, published on July 1, 1997).

Scheele *et al.*, teach synthesis of full-length, double-stranded DNA from a single stranded linear DNA template.

Regarding claims 1 and 10, Scheele *et al.*, teach a Poly (dT) primer with 5-30 T (see column 5, Table 1 and lines 55-57). When the Poly (dT) primer with 18 T is used, this primer is completely hybridize with 18 A in 3' end of SEQ ID NO: 1 of this instant application. Thus Scheele *et al.*, disclose a sequence (ie., the Poly (dT) primer with 18 T) that hybridizes to a sequence in (a) of claim 1 under stringent conditions as recited in (b) of claim 1. Since the Poly (dT) primer is a DNA, claim 10 is anticipated by Scheele *et al.*.

Therefore, Scheele *et al.*, teach all limitations recited in claims 1 and 10.

Response to Arguments

In page 10, last paragraph bridging to page 11, first paragraph of applicant's remarks, applicant argues that "SCHEELE et al. make no mention suggestion of the claimed sequence".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because Scheele *et al.*, teach all limitations recited in claims 1 and 10 (see above rejection under 35 U.S. C 102).

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

15. Claims 32 and 33 are allowed over prior art in the record.

16. No claim is allowed.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
January 26, 2005


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

1/31/05